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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/841,836	04/25/2001	Bruce L. Roberts	GA0229	5822

24536 7590 02/23/2005

GENZYME CORPORATION  
LEGAL DEPARTMENT  
15 PLEASANT ST CONNECTOR  
FRAMINGHAM, MA 01701-9322

EXAMINER

CHEN, STACY BROWN

ART UNIT PAPER NUMBER

1648

DATE MAILED: 02/23/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/841,836

Applicant(s)

ROBERTS ET AL.

Examiner

Stacy B Chen

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 06 December 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) 7-20 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-6 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

**DETAILED ACTION**

1. Applicant's response and amendment filed December 6, 2004 is acknowledged and entered. Claims 1-20 are pending. Claims 1-6 are under examination. Claims 7-20 remain withdrawn from consideration being drawn to non-elected inventions. The only rejections in this application are the rejection of claims 1, 5 and 6 under 35 U.S.C. 102(e) as anticipated by Blaschuk *et al.* (US Patent 6,358,920), and the rejection of claims 2-4 under 35 U.S.C. 103(a) as obvious over Mounts *et al.* (WO 98/52615) in view of Blaschuk and Lisziewicz *et al.* (US Patent 6,420,176).

***Claim Rejections - 35 USC § 102 and 103***

2. Claims 1, 5 and 6 remain rejected under 35 U.S.C. 102(e) as anticipated by Blaschuk *et al.* (US Patent 6,358,920, herein, "Blaschuk"). Claims 2-4 remain rejected under 35 U.S.C. 103(a) as obvious over Mounts *et al.* (WO 98/52615) in view of Blaschuk and Lisziewicz *et al.* (US Patent 6,420,176). The claims have not been amended and remain drawn to the same subject matter as addressed in the previous Office action. Applicant's arguments have been carefully considered but fail to persuade. The arguments presented for the 102 and 103 rejections are the same and will be addressed together.

Applicant argues that a close reading of the Blaschuk patent (6,358,920) does not teach that adenoviral vectors may be targeted for delivery using microspheres/beads. Applicant asserts that Blaschuk teaches away from the instant invention by teaching two independent modes of delivery of the polynucleotides: viral vectors and microsphere/beads, but not in combination.

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Applicant argues that in view of the deficiencies of Blaschuk, the rejection under 35 U.S.C. 102(d) and 103(a) should be withdrawn.

In response, the Office has considered Applicant's arguments regarding the teachings of col. 68, lines 10-37. Blaschuk teaches that polynucleotides may function as modulating agents (col. 68, lines 10-11). Also taught is that modulating agents may be linked to a support molecule or a solid support (col. 15, lines 5-7). Polynucleotides incorporated into vectors would still be considered modulating agents, and whatever uses described for the modulating agent as a polynucleotide would convey to the modulating agent as a vector. One would recognize from Blaschuk's teachings that the polynucleotides or vectors containing them may be linked to a support molecule or solid support, such as a bead or other support listed in col. 68. Therefore, Blaschuk contemplates vectors comprising the subject polynucleotides attached to a support molecule.

### ***Conclusion***

3. No claim is allowed. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

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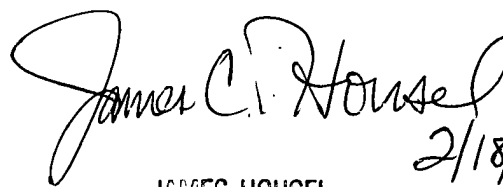
however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stacy B. Chen whose telephone number is 571-272-0896. The examiner can normally be reached on M-F (7:00-4:30). If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James C. Housel can be reached on 571-272-0902. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.



Stacy B. Chen  
February 17, 2005

  
2/18/05

JAMES HOUSEL  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 1600